



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 02/28/17
LAST REVIEW DATE: 09/18/18
LAST CRITERIA REVISION DATE: 10/04/17
ARCHIVE DATE:

LIVER TRANSPLANT AND COMBINED LIVER-KIDNEY TRANSPLANT

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Liver transplantation is performed as a treatment of last resort for individuals with end-stage liver disease. Combination liver-kidney transplantation is performed as a treatment of last resort for individuals with end-stage liver disease and advanced irreversible kidney disease.

Liver transplantation may be performed with liver donation after brain or cardiac death or with a liver segment donation from a living donor.

Criteria:

Liver transplants will be reviewed by the medical director(s) and/or clinical advisor(s).

Pre-Transplantation Evaluation:

- Pre-transplantation evaluation criterion is met with documentation of psychosocial screen and **ALL** of the following:
 1. Drug/alcohol screen with documentation of **ONE** of the following:
 - No drug/alcohol abuse by history
 - Drug and alcohol free for a period greater than or equal to 6 months
 2. Behavioral health disorder screening with documentation of **ONE** of the following:
 - No behavioral health disorder by history
 - Behavioral health disorder by history with documentation of **BOTH** of the following:
 - No severe psychosis/personality disorder
 - Mood/anxiety disorder excluded/treated
 3. Individual understands surgical risk and post procedure compliance and follow-up
 4. Adequate social/family support

LIVER TRANSPLANT AND COMBINED LIVER-KIDNEY TRANSPLANT (cont.)

Criteria: (cont.)

- Liver transplant using a cadaver or living donor for an individual with end-stage liver failure due to irreversibly damaged liver is considered **medically necessary** with documentation of **ALL** of the following:
 1. Pretransplantation evaluation criteria above is met
 2. Individual has **ANY** of the following conditions to include, *but not limited to*:
 - Hepatocellular disease
 - Alcoholic liver disease
 - Viral hepatitis (either A, B, C, or non-A, non-B)
 - Autoimmune hepatitis
 - Alpha-1 antitrypsin deficiency
 - Hemochromatosis
 - Non-alcoholic steatohepatitis
 - Protoporphyrria
 - Wilson's disease
 - Cholestatic liver disease
 - Primary biliary cirrhosis
 - Primary sclerosing cholangitis with development of secondary biliary cirrhosis
 - Biliary atresia
 - Vascular disease
 - Budd-Chiari syndrome
 - Hepatocellular carcinoma, primary
 - Inborn errors of metabolism
 - Trauma and toxic reactions
 - Miscellaneous
 - Familial amyloid polyneuropathy
- Liver transplantation is considered **medically necessary** in individuals with polycystic disease of the liver who have massive hepatomegaly causing obstruction or functional impairment.
- Liver transplant for individuals with unresectable hilar cholangiocarcinoma is considered **medically necessary**.
- Liver transplantation is considered **medically necessary** in pediatric individuals with non-metastatic hepatoblastoma.



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Criteria: (cont.)

- Liver retransplantation is considered **medically necessary** with documentation of **ANY** of the following:
 1. Primary graft non-function
 2. Hepatic artery thrombosis
 3. Chronic rejection
 4. Ischemic type biliary lesions after donation after cardiac death
 5. Recurrent non-neoplastic disease causing graft failure
- Combined liver-kidney transplantation is considered **medically necessary** in individuals who qualify for liver transplantation and have advanced irreversible kidney disease.
- Liver transplantation is considered **not medically necessary** for the following:
 1. Individuals with hepatocellular carcinoma that has extended beyond the liver
 2. Individuals with ongoing alcohol and/or drug abuse
- Liver transplantation for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to:*

- Intrahepatic cholangiocarcinoma
- Neuroendocrine tumors metastatic to the liver



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Resources:

Literature reviewed 09/18/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 7.03.06 BCBS Association Medical Policy Reference Manual. Liver Transplant and Combined Liver-Kidney Transplant. Re-issue date 08/09/2018, issue date 12/01/1995.
2. McKesson InterQual® Care Planning Procedures. Transplantation, Liver.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í'í hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

